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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,539	KARLIK ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) *14,32,35 and 39-91* is/are withdrawn from consideration.

5)☒ Claim(s) *13* is/are allowed.

6)☒ Claim(s) *1-12,15-31,33,34 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :18 January 2006 and 28 November 2006.

DETAILED ACTION

Status of the Claims

1. Claims 1-91 are pending in the application, with claims 39-91 having been withdrawn, in response to the restriction requirement submitted on December 15, 2006. Accordingly, claims 1-38 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election without traverse of Group I, namely claims 1-38, in the reply filed on February 15, 2007 is acknowledged.

3. Applicant's election without traverse of the species of (1) a compound of formula IC, where R^x is hydroxyl, as a species of a compound, (2) prednisolone as a species of an anti-inflammatory agent or immunosuppressant, and (3) multiple sclerosis as a species of a condition which demyelinates cells, in the reply filed on February 15, 2007 is acknowledged.

Claims 1-13, 15-31, 33-34, and 36-38 are read to draw on the elected species of a compound of formula IC, where R^x is hydroxyl.

Claims 24-25 are read to draw on the elected species of multiple sclerosis.

Claims 29-31 and 33-34 is read to draw on the elected species of prednisolone.

Claims 14, 32 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on February 15, 2007.

The elected species of a compound of formula IC, where R^x is hydroxyl, was found to be free of the prior art and thus the search was broadened to the compound of formula I.

The restriction requirement and the election of species requirement of (1) a compound of formula IC, where R^x is hydroxyl, as a species of a compound, (2) prednisolone as a species of an anti-inflammatory agent or immunosuppressant, and (3) multiple sclerosis as a species of a condition which demyelinates cells are still deemed proper and are therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on January 18, 2006 and November 28, 2006 is acknowledged.

Specification

4. The use of the trademarks Antegren and Copaxone has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-12, 15-22-31, 33-34, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorsett et al. (US 6,489,300) in view of Kawamura et al. (US 2002/0161006).

Thorsett et al. teach a method of treating multiple sclerosis comprising administering VLA-4 inhibitors to humans (abstract). The compounds taught are of formula I, which meets the limitations of the compounds of formula I, IA, II, IIA, IB, and IIB of the instant claims 1-5 and 15, respectively (page 235, Formula I). The compound of formula I, namely N-(toluene-4-sulfonyl)-L-prolyl-L-4-(4-methylpiperazin-1-ylcarbonyloxy)phenylalanine ethyl ester, meets the limitations of instant claim 22 (column 8, lines 36-37). The compounds are administered intravenously (page 136, line 5). For intravenous administration, the dose ranges from 20 μg to 500 μg per kilogram body weight (page 153, lines 14-16).

Thorsett et al. do not teach prednisolone.

Kawamura et al. teach a composition comprising of prednisolone and adhesion molecule inhibitors, e.g. VLA-4 antagonist, can be used for treating multiple sclerosis via parenteral administration in humans (page 1, paragraph [0001]; page 9, paragraph [0164]; page 12, paragraph [0200]; and page 23, paragraph [0305]).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the VLA-4 inhibitors of Thorsett et al. to contain prednisolone because the compounds of Kawamura et al. contain prednisolone and according to Kawamura et al., compositions containing prednisolone has been used for treating multiple sclerosis.

The motivation to combine the compounds of Thorsett et al. to the compounds of Kawamura et al. is that the compounds of Kawamura et al. contain prednisolone, which has been used for treating multiple sclerosis.

Regarding the method of promoting remyelination of nerve cells as recited in instant claims 1-38,

Regarding the chronic administration of the compound as recited in instant claims 27-28, Thorsett et al. teach administration of the compound through a transdermal delivery device to provide continuous infusion of the compounds in controlled amounts (page 143, lines 28-31). Since Thorsett et al. teach providing continuous infusion of the compounds, it would be obvious to one skilled in the art to chronically administer the compound using such a delivery device.

Regarding the administration results in an effective blood level of the compound of $\geq$ 10 ng/ml as recited in instant claim 37, Thorsett et al. teaches for intravenous administration, the dose ranges from 20 μg to 500 μg per kilogram body weight, which meets the limitations of the instant claims (page 153, lines 14-16). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of the compound for intravenous administration provided in a composition, according to the guidance set forth in Thorsett et al., to provide the desired blood level of the compound following intravenous administration of the compound. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-5, 13, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10 of Ashwell et al. (US 6,291,453), claims 1-2 and 16 of Thorsett et al. (US 6,362,341), claims 1-2 and 15-16 of Ashwell et al. (US 6,436,904), claims 1 and 11 of Thorsett et al. (US 6,492,421), claims 1-2 and 10-11 of Thorsett et al. (US 6,525,026), claims 1-2 of Dappen et al. (US 6,559,127), claims 1-2 and 14 of Thorsett et al. (US 6,583,139), claims 1-2 and 11 of Thorsett et al. (US 6,586,602), claims 1-2 of Thorsett et al. (US 6,900,179), claims 1-2 and 9-10 of Ashwell et al. (US 6.949,570), claims 1-2 and 10 of Thorsett et al. (US 7,030,114), and claims 1-2 and 9-11 of Dappen et al. (US 7,166,580).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 10 of Ashwell et al. (US 6,291,453) are directed to compounds

of formula I and pharmaceutical compositions of compounds of formula I, claims 1-2 and 16 of Thorsett et al. (US 6,362,341) are directed to compounds of formula I, formula II and formula III, claims 1-2 and 15-16 of Ashwell et al. (US 6,436,904) are directed to compounds of formula I and formula IA and pharmaceutical compositions of compounds of formula I and formula IA, claims 1 and 11 of Thorsett et al. (US 6,492,421) are directed to compounds of formula I and pharmaceutical compositions of compounds of formula IA, claims 1-2 and 10-11 of Thorsett et al. (US 6,525,026) are directed to compounds of formula I and formula IA and pharmaceutical compositions of compounds of formula I and formula IA, claims 1-2 of Dappen et al. (US 6,559,127) are directed to compounds of formula I and formula IA, claims 1-2 and 14 of Thorsett et al. (US 6,583,139) are directed to compounds of formula I and formula IA and pharmaceutical compositions of compounds of formula I or formula IA, claims 1-2 and 11 of Thorsett et al. (US 6,586,602) are directed to compounds of formula I and formula IA and pharmaceutical compositions of compounds of formula I or formula IA, claims 1-2 of Thorsett et al. (US 6,900,179) are directed to compounds of formula I and formula IA, claims 1-2 and 9-10 of Ashwell et al. (US 6.949,570) are directed to compounds of formula I and formula IA and pharmaceutical compositions of compounds of formula I and formula IA, claims 1-2 and 10 of Thorsett et al. (US 7,030,114) are directed to compounds of formula I and formula IA and pharmaceutical compositions of compounds of formula IA, and claims 1-2 and 9-11 of Dappen et al. (US 7,166,580) are directed to compounds of formula I and formula II and pharmaceutical compositions of compounds of formula I or formula II, which are the same compounds and pharmaceutical compositions of Formula I, IA, II, IIA, IB, IC, and IIB used in the methods of promoting remyelination of instant claims 1-5, 13, and 15, respectively. Thus the compounds

and pharmaceutical compositions of formula I, formula IA, formula II, and formula III are not patentably distinct between Ashwell et al. (US 6,291,453), Thorsett et al. (US 6,362,341), Ashwell et al. (US 6,436,904), Thorsett et al. (US 6,492,421), Thorsett et al. (US 6,525,026), Dappen et al. (US 6,559,127), Thorsett et al. (US 6,583,139), Thorsett et al. (US 6,586,602), Thorsett et al. (US 6,900,179), Ashwell et al. (US 6.949,570), Thorsett et al. (US 7,030,114), Dappen et al. (US 7,166,580), and the instant application.

7. Claims 1-5, 13, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-21 of Ashwell et al. (US 6,291,453), claims 11 and 13 of Thorsett et al. (US 6,362,341), claims 28-29 of Ashwell et al. (US 6,436,904), claims 22 and 34-35 of Thorsett et al. (US 6,492,421), claim 18 of Thorsett et al. (US 6,525,026), claim 9 of Dappen et al. (US 6,559,127), claims 13 and 15 of Thorsett et al. (US 6,583,139), claims 10 and 12 of Thorsett et al. (US 6,586,602), claim 13 of Thorsett et al. (US 6,900,179), and claims 11-12 of Thorsett et al. (US 7,030,114) in view of Thorsett et al. (US 6,489,300).

Thorsett et al. (US 6,489,300) teach a method of treating inflammatory disorders such as multiple sclerosis using the compounds of Formula (I) (abstract). Thorsett et al. (US 6,489,300) also teach compounds which bind to VLA-4 and a method to assay for the presence of VLA-4 in a sample (column 3, lines 6-8). Furthermore, multiple sclerosis is the result of an autoimmune reaction in which leukocytes attack and initiate the destruction of myelin (column 97, lines 1-2).

According to the teachings of Thorsett et al. (US 6,489,300), the method for binding VLA-4, the method for treatment of an inflammatory disease or condition, and the method for treating a disease mediated by VLA-4 in Ashwell et al. (US 6,291,453), Thorsett et al. (US

6,362,341), Ashwell et al. (US 6,436,904), Thorsett et al. (US 6,492,421), Thorsett et al. (US 6,525,026), Dappen et al. (US 6,559,127), Thorsett et al. (US 6,583,139), Thorsett et al. (US 6,586,602), Thorsett et al. (US 6,900,179), and Thorsett et al. (US 7,030,114) are rendering obvious over the methods of promoting remyelination of instant claims 1-5, 13, and 15.

8. Claims 1-5, 13, 15, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, and 7 of Yednock et al. (US 6,939,855) in further view of Thorsett et al. (US 6,489,300).

Yednock et al. (US 6,489,300) teach compounds that modulate alpha-4/beta-1 integrin will also modulate alpha-9 integrin (column 19, lines 26-28). Thorsett et al. (US 6,489,300) teach a method of treating inflammatory disorders such as multiple sclerosis using the compounds of Formula (I) (abstract). In Thorsett et al. (US 6,489,300), the prior art teaches VLA-4 contains integrins of an alpha-4 chain and a beta-1 chain (column 2, line 9). VLA-4 is present on endothelial cells and that in inflammation, leukocytes adhere to VLA-4 (column 2, lines 24-26). Thus, multiple sclerosis is the result of an autoimmune reaction in which leukocytes attack and initiate the destruction of myelin through binding of leukocytes to VLA-4 (column 97, lines 1-2).

According to the teachings of Yednock et al. (US 6,489,300) and Thorsett et al. (US 6,489,300), the method of treating an inflammatory disorder in claim 22 is rendered obvious over the methods of promoting remyelination of instant claims 1-5, 13, 15, and 22.

9. Claims 1-5, 13, 15, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 12 of Thorsett et al. (US 6,489,300).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2 of Thorsett et al. are directed at a compound of Formula (I) and Formula (IA) and claim 12 is directed at the compound N-(toluene-4-sulfonyl)-L-prolyl-L-4-(4-methylpiperazin-1-ylcarbonyloxy)phenylalanine ethyl ester, which are the same compounds of Formula I, IA, II, IIA, IB, IC, and IIB as well as of N-(toluene-4-sulfonyl)-L-prolyl-L-4-(4-methylpiperazin-1-ylcarbonyloxy)phenylalanine ethyl ester used in the methods of promoting remyelination of instant claims 1-5, 13, 15, and 22, respectively. Thus the compounds of Formula (I) and Formula (IA) are not patentably distinct between Thorsett et al. and the instant application.

10. Claims 1-5, 13, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 14, and 17 of copending Application Thorsett et al. (US 2003/0065185) and claims 35-36 of copending Application Thorsett et al. (US 2005/0222119).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2 and 14 and 17 of Thorsett et al. (US 2003/0065185) are directed at a compounds of Formula (I) and Formula (IA) and pharmaceutical compositions of Formula (I) and Formula (IA) and claims 35-36 of Thorsett et al. (US 2005/0222119) are directed at pharmaceutical compositions of Formula (I) and Formula (IA), which are the same compounds and pharmaceutical compositions of Formula I, IA, II, IIA, IB, IC, and IIB used in the methods of promoting remyelination of instant claims 1-5, 13, and 15, respectively. Thus the compounds and pharmaceutical compositions of Formula (I) and Formula (IA) are not patentably distinct

between Thorsett et al. (US 2003/0065185), Thorsett et al. (US 2005/0222119), and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

11. Claims 1-5, 13, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of copending Application Yednock et al. (US 2005/0272668) in view of Thorsett et al. (US 6,489,300) and Yednock et al. (US 6,939,855).

Thorsett et al. (US 6,489,300) teach a method of treating inflammatory disorders such as multiple sclerosis using the compounds of Formula (I) (abstract). In Thorsett et al. (US 6,489,300), the prior art teaches VLA-4 contains integrins of an alpha-4 chain and a beta-1 chain (column 2, line 9). VLA-4 is present on endothelial cells and that in inflammation, leukocytes adhere to VLA-4 (column 2, lines 24-26). Thus, multiple sclerosis is the result of an autoimmune reaction in which leukocytes attack and initiate the destruction of myelin through binding of leukocytes to VLA-4 (column 97, lines 1-2). Yednock et al. (US 6,489,300) teach compounds that modulate alpha-4/beta-1 integrin will also modulate alpha-9 integrin (column 19, lines 26-28).

According to the teachings of Thorsett et al. (US 6,489,300) and Yednock et al. (US 6,489,300), the method of treating an inflammatory disorder in claim 22 is rendered obvious over the methods of promoting remyelination of instant claims 1-5, 13, and 15.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

12. Claims 1-5, 13, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 16 of copending Application Thorsett et al. (US 2003/0065185) in view of Thorsett et al. (US 6,489,300).

Thorsett et al. (US 6,489,300) teach a method of treating inflammatory disorders such as multiple sclerosis using the compounds of Formula (I) (abstract). Thorsett et al. (US 6,489,300) also teach compounds which bind to VLA-4 and a method to assay for the presence of VLA-4 in a sample (column 3, lines 6-8). Furthermore, multiple sclerosis is the result of an autoimmune reaction in which leukocytes attack and initiate the destruction of myelin (column 97, lines 1-2).

According to the teachings of Thorsett et al. (US 6,489,300), the method for binding VLA-4 of claim 13 and the method of treating an inflammatory condition of claim 16 in Thorsett et al. (US 2003/0065185) are rendering obvious over the methods of promoting remyelination of instant claims 1-5, 13, and 15.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

13. Claims 1-5, 13, 15, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-36 and 56 of copending Application Thorsett et al. (US 2004/0014677) in view of Thorsett et al. (US 6,489,300).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 35-36 of Thorsett et al. are directed at a method for treating an inflammatory condition comprising administering a compound of Formula (I) and Formula (IA) and claim 56 is directed at a method of treating an inflammatory condition comprising administering the compound N-(toluene-4-sulfonyl)-L-prolyl-L-4-(4-methylpiperazin-1-

ylcarbonyloxy)phenylalanine ethyl ester, which are the same compounds of Formula I, IA, II, IIA, IB, IC, and IIB as well as N-(toluene-4-sulfonyl)-L-prolyl-L-4-(4-methylpiperazin-1-ylcarbonyloxy)phenylalanine ethyl ester used in the methods of promoting remyelination of instant claims 1-5, 13, 15, and 22, respectively.

Furthermore, Thorsett et al. (US 6,489,300) teach a method of treating inflammatory disorders such as multiple sclerosis using the compounds of Formula (I) (abstract). Multiple sclerosis is the result of an autoimmune reaction in which leukocytes attack and initiate the destruction of myelin (column 97, lines 1-2).

Thus the methods comprising administration of compounds of Formula (I) and Formula (IA) are not patentably distinct between Thorsett et al. (US 2004/0014677) and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

14. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER